We claim:

1. A process for the industrial synthesis of strontium ranelate of formula (I):

and its hydrates,

5 wherein the compound of formula (IV):

$$RO_2C$$
 CO_2R (IV),

wherein R represents linear or branched (C₁-C₆)alkyl,

is reacted with malononitrile of formula (V):

in methanol,

in the presence of morpholine in an amount greater than 0.95 mol per mol of compound of formula (IV),

to yield the compound of formula (VI):

wherein R is as defined hereinbefore,

which is then reacted with sulphur in an amount greater than 0.95 mol per mol of compound of formula (IV);

the reaction mixture is then heated at reflux; and the compound thereby obtained is isolated by precipitation in the presence of water, followed by filtration, to yield the compound of formula (III):

$$RO_2C$$
 NH_2
 $(III),$

wherein R is as defined hereinbefore,

which is reacted with a compound of formula (VII):

wherein R' represents linear or branched (C₁-C₆)alkyl,
in the presence of a catalytic amount of a C₈-C₁₀-type quaternary ammonium compound,
and in the presence of potassium carbonate,
at the reflux of an organic solvent;
the reaction mixture is subsequently filtered;
the mixture is then concentrated by distillation;
a co-solvent is then added,

and the reaction mixture is cooled and filtered to yield, after drying of the powder thereby obtained, the compound of formula (II):

$$RO_2C$$
 CN
 CO_2R'
 CO_2R'
 CO_2R'

wherein R and R' are as defined hereinbefore,

which is reacted with strontium hydroxide in an amount greater than or equal to 2 mol per mol of compound of formula (II),

at the reflux of water,

for at least 5 hours;

the precipitate obtained is then filtered off whilst hot;

the cake obtained is washed with boiling water
to yield, after drying of the powder thereby obtained, the compound of formula (I) and its
hydrates,

it being understood that a C_8 - C_{10} -type quaternary ammonium compound is a compound of formula (A) or a mixture of compounds of formula (A):

$$R_1 R_2 R_3 R_4 - N^{+} X$$
 (A)

wherein R_1 represents (C_1-C_6) alkyl, R_2 , R_3 and R_4 , which are the same or different, each represent (C_8-C_{10}) alkyl, and X represents a halogen atom.

2. Process for the industrial synthesis of compounds of formula (III):

$$RO_2C$$
 CN (III), RO_2C S NH_2

wherein R represents linear or branched (C₁-C₆)alkyl,

wherein the compound of formula (IV):

$$RO_2C$$
 CO_2R (IV),

5

wherein R is as defined hereinbefore, is reacted with malononitrile of formula (V):

in methanol,

in the presence of morpholine in an amount greater than 0.95 mol per mol of compound of formula (IV),

to yield the compound of formula (VI):

wherein R is as defined hereinbefore,

which is then reacted with sulphur in an amount greater than 0.95 mol per mol of compound of formula (IV);

the reaction mixture is then heated at reflux;

and the compound of formula (III) thereby obtained is isolated by precipitation in the presence of water, followed by filtration.

3. Process for the industrial synthesis of strontium ranelate of formula (I):

and its hydrates,

5

10

15

wherein the compound of formula (II):

$$RO_2C$$
 CN
 CO_2R'
 CO_2R'
 CO_2R'

wherein R and R', which are the same or different, each represent linear or branched (C₁-C₆)alkyl,

is reacted with strontium hydroxide in an amount greater than or equal to 2 mol per mol of compound of formula (II),

at the reflux of water,

for at least 5 hours;

the precipitate obtained is then filtered off whilst hot;

the cake obtained is washed with boiling water to yield, after drying of the powder thereby obtained, the compound of formula (I) and its hydrates.

4. Synthesis process according to claim 1, wherein the amount of methanol used in the synthesis of the compound of formula (III) is from 1 to 3 ml per gram of compound of formula (IV).

5

- 5. Synthesis process according to claim 1, wherein the temperature of reaction between the compounds of formulae (IV) and (V) is less than 50°C.
- 6. Synthesis process according to claim 1, wherein the refluxing time for the reaction between the compound of formula (VI) and sulphur is between 1 hour 30 minutes and 3 hours.
 - 7. Synthesis process according to claim 1, wherein the amount of potassium carbonate used in the synthesis of the compound of formula (II) is from 2 to 3 mol per mol of compound of formula (III).
- 8. Synthesis process according to claim 1, wherein the amount of compound of formula (VII) is from 2 to 3 mol per mol of compound of formula (III).
 - 9. Synthesis process according to claim 1, wherein the initial volume of organic solvent used in the reaction of the compound of formula (III) with the compound of formula (VII) is from 6 to 12 ml per gram of compound of formula (III).
- 10. Synthesis process according to claim 1, wherein the organic solvent used in the reaction of the compound of formula (III) with the compound of formula (VII) is acetone or acetonitrile.
 - 11. Synthesis process according to claim 1, wherein the co-solvent used in the isolation of the compound of formula (II) is methanol.

- 12. Synthesis process according to claim 1, wherein the compound of formula (II) obtained has a chemical purity greater than 98 %.
- 13. Synthesis process according to claim 1, wherein the amount of water used in the reaction of the compound of formula (II) with strontium hydroxide is greater than or equal to 8 ml per gram of compound of formula (II).
- 14. Synthesis process according to claim 1, wherein the amount of strontium hydroxide is from 2 to 2.5 mol per mol of compound of formula (II).
- 15. Synthesis process according to claim 1, wherein R represents methyl and R' represents methyl or ethyl.

10

5